Consumer and Corporate Affairs Canada | Consommation et Corporations Canada

(11) (A) No. 1 150 122

(45) ISSUED 830719

(52) CLASS 128-81

(51) INT. CL. ^{3} A61M 5/00

(19) (CA) **CANADIAN PATENT** (12)

(54) DOUBLE-LUMEN CANNULA

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(73) Granted to Vas-Cath of Canada Limited
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(21) APPLICATION No. 350,001

(22) FILED 800416

No. OF CLAIMS 3

Canada

DISTRIBUTED BY THE PATENT OFFICE, OTTAWA.
CCA-274 (11-82)

ABSTRACT OF THE DISCLOSURE

A dual lumen cannula for use in haemodialysis by inserting the cannula into the subclavian vein of a patient to contemporaneously remove blood from the vein for treatment and to return treated blood to the vein downstream from the point of removal. The cannula includes inner and outer lumens and blood is withdrawn through the space between the lumens. Treated blood is returned to the inner lumen. The outer lumen is shaped to have a curvature similar to that of the portion of the vein receiving the cannula and is sufficiently flexible to be straightened during insertion without damage or kinking. The outer lumen has a tapered distal end portion which fits snugly about a part of the inner lumen and defines openings adjacent this end portion to withdraw blood from the vein. Similarly the inner lumen defines openings in a portion outside the outer lumen for returning blood downstream from the point of removal of the blood. The inner lumen can be withdrawn between haemodialysis treatments leaving only the outer lumen in position and heparinized physiological saline solution can be injected into the outer lumen to prevent blood clotting. If desired, the inner lumen may be left in place between treatments and both inner and outer lumens kept patent with heparinization.

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This invention relates to a dual lumen cannula, and more particularly to such a cannula for insertion into the subclavian vein of a patient to facilitate haemodialysis treatments.

For regular haemodialysis, permanent vascular access is normally provided by means of a surgically constructed arterio-venous fistula, created if possible in advance of need.

The conventional method of conducting haemodialysis on a patient is to introduce into an arterialized vein, normally a lower arm vein, one or two blood flow needles. Blood is removed from the patient to an exterior haemodialysis machine and then the treated blood is returned to the patient at substantially the same location. At least one puncture of the vein needs to be made for such catheter insertion whenever the patient undergoes a haemodialysis treatment. Commonly two separate needle devices are used, one for blood outflow and the other for blood return, although there is a growing interest in dual lumen catheters which have the advantage that they require only one vein puncture. Examples of conventional co-axially arranged metal cannulae for use in a limb of the patient are to be found in U.S. patents 4,037,599 to Raulerson; 4,073,297 to Kopp; 4,134,402 to Mahurkar; and 4,096,860 to McLaughlin. All of these examples of prior art show a rigid, metal

needle-type cannulae for temporary use during the actual haemodialysis or transfusion etc. These devices are removed once the procedure is completed. None of the devices is suitable for insertion into a subclavian vein.

Although the arterio-venous fistula is the standard and accepted method for permanent vascular access, some patients experience end stage renal failure without warning, and established fistulae may fail unexpectedly. With the growth of large programmes for long-term peritoneal dialysis, an increasing number of patients must be transferred at short notice to haemodialysis because of peritonitis. Such patients do not usually have arterio-venous fistulae constructed in advance, since many of them will never need them. Patients on long-term peritoneal dialysis may also need short-term haemodialysis while they undergo abdominal surgery. Transplant recipients whose arterio-venous fistulae have thrombosed may develop acute renal failure. For all these categories of patients, the silastic teflon shunt, though immediately usable, wastes blood vessels and may not be feasible in patients whose access sites have already been used. Temporary peritoneal dialysis is not always a suitable alternative.

There is thus a need for a simple, immediately usable vascular access method which does not destroy blood vessels, and does not limit the patient's mobility. Tempor-

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ary vascular access for haemodialysis can be obtained with a femoral cannula introduced by the Seldinger technique, normally inserted in the femoral vein.

With such prior art devices, the patient must be prepared and the catheter applied carefully, by medically trained personnel, prior to every haemodialysis use. For patients with absence of renal function, this can be several times per week. The preparation and application is time-consuming and difficult to perform on an emergency basis. The cannula cannot be left in situ after dialysis if the patient is to remain mobile. Moreover, repeated insertions lead to the build-up of scar tissue at the access sites of the patient. Some means of readily usable, semi-permanent vascular access would be preferable.

The present invention is intended to provide an indwelling subclavian cannula which is particularly suitable for temporary haemodialysis. When not in use, the cannula remains in situ without unduly restricting the mobility or activities of the patient. Accordingly the invention provides a dual lumen cannula, having inner and outer lumens located co-axially so that only one insertion into the vein of the patient is required. Both of the lumens are elongated and the inner lumen is more flexible than the outer lumen which is pre-formed to have an arcuate curve reflecting the general shape of the subclavian vein. Although the cannula is

inserted with the inner lumen inside the outer lumen, the inner lumen can be replaced without removing the outer lumen. Also, when not in use, the inner lumen is removed and heparinized physiological saline solution can be injected periodically into the outer lumen. The facility to remove the inner lumen limits the possibility of blood clotting when the cannula is not in use.

The invention will be better understood with reference to the following description taken in combination with the drawings, in which:

Fig. 1 is a diagramatic representation of a preferred embodiment of a dual lumen cannula according to the invention positioned in the subclavian vein of a patient and shown in a storage mode between haemodialysis treatments;

Fig. 2 is a side view of the preferred embodiment of dual lumen cannula according to the invention;

Fig. 3 is a sectional end view on line 3-3 of Fig. 2; and

Fig. 4 is a sectional side view to an enlarged scale and showing the tip or leading end of the cannula.

Reference is first made to Fig. 1 which shows the preferred embodiment of subclavian haemodialysis cannula of the present invention in position on a patient in a mode between haemodialysis treatments. The cannula is secured in position by means of a conventional adhesive dressing 20 with the cannula

positioned through the dressing. The cannula is shown generally by the numeral 22 and consists of an end portion 24 coupled to an outer tube or lumen 26, and also having an inner tube or lumen which is not shown in this figure but which will be described subsequently. The inner lumen is positioned within the outer lumen 26 during haemodialysis procedures.

Reference is next made to Fig. 2 to more fully describe the dual lumen cannula according to the invention. As seen in Fig. 2 the outer lumen 26 is curved and terminates at its distal end in a tapered portion 28 which fits snugly about an outer end of an inner tube or lumen 30. As seen in Fig. 3, the inner lumen 30 fits loosely within the outer lumen 26 to permit flow between the lumens as will be described.

Returning to Fig. 2, the outer lumen 26 ends at its inner end in a bulbous portion 32 which receives one end of the flexible tubular connector 34. This connector is retained on the lumen 26 by a band 36 which is shrunk on the connector and combines with the bulbous portion 32 to make a strong mechanical joint between the connector 34 and the lumen 26.

At its other end, the connector 34 is designed to receive a male end portion of a Y-fitting 38 having a first branch 40 and a second branch 42. A flexible tube

44 is pushed on an end of the branch 40 and, at its other end, receives a first part 46 of a luer fitting which is conventionally used in medical equipment associated with a cannula of this type. The other branch 42 is associated with a further flexible tube 48 and this receives a further first part 50 of another luer connector. The inner lumen 30 is positioned inside the outer lumen 36 and passes through the connector 34, second branch 42 of the Y-fitting 38, through the flexible tube 48, and through the first part 50 of the luer connector. The inner luer has attached to it a second part 52 of the luer connector and this can be threadably engaged on the part 50 and includes a tubular part 54 projecting outwardly for receiving tubing from a haemodialysis machine or the like in conventional manner. A similar fitting would be provided on the first part 46 of the luer connector on the branch 40 simply for the purpose of connecting tubing. With this arrangement set up and positioned on the patient as shown in Fig. 1, it will be appreciated that blood can be withdrawn through the space between the inner and outer cannulae and through the branch 40 of the Y-fitting to apparatus (not shown) for haemodialysis treatment. The treated blood is then returned via the lower connector part 52 and inner lumen 30. In order to facilitate flow into and out of the lumens 26, 30 they are perforated as shown in Fig. 4 which is drawn to a

larger scale than Fig. 2. It will be seen that the inner lumen 30 projects beyond the outer lumen 26 and is perforated by openings 56. Similarly, the outer lumen 26 is perforated by openings 58 and the general arrangement of flow is indicated by arrows. It should be noted that the distal end of the inner lumen 30 is tapered inwardly and this is done to cause the lumen to fit snugly about a guide wire used for insertion as will be described.

The procedure for using the cannula will be described with reference particularly to Figs. 1 and 2. After first preparing the patient for the procedure, the patient lies on his back with his face turned away from the site. Taking the normal medical precautions, an incision is made and a fine wire is inserted into the subclavian vein using the Seldinger technique. The cannula can then be inserted by sliding it over the wire with the wire engaged inside the inner lumen 30. The tapered end of the lumen facilitates entry as does the tapered end of the outer lumen 26. The cannula is gradually worked into the subclavian vein and the residual shape of the outer lumen, although flexible for insertion, naturally takes up the shape of the vein. The purpose of this shaping is twofold. Firstly it permits the use of a relatively rigid outer lumen which resists kinking significantly while nevertheless permitting sufficient resilience for insertion. This resistance to

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kinking is of course very important and not readily achieved without this combination of curvature and rigidity.

After insertion the equipment used for haemodialysis is connected to the cannula using the usual precautions to avoid embolus etc. Flow can then take place from the patient to the equipment essentially by the outer lumen and then returned within the inner lumen.

After treatment the inner lumen can be withdrawn, and the branch 42 of the Y-fitting sealed both by a luer cap placed on the first part 50 of the luer connector and by a sliding clip of the type indicated by numeral 58 in Fig. 2 and identified as 60 in Fig. 1. This double closure is of course for safety reasons so that should the luer connector fail, the clip will continue to seal the branch 42.

The branch 40 is treated slightly differently. The cap placed on the first part 46 of the luer connector consists of a cap having a diaphragm which can be perforated by a needle for injecting heparin containing physiological saline solution. This is done to prevent clotting at the end of the outer lumen while this lumen remains in place within the vein. It will be appreciated that because the inner lumen has been removed, there is no location where blood could be trapped and where this blood would clot. All of the inner part of the outer cannula 26 receives and is

washed by the heparin containing liquid. Also, after inserting the liquid, a further clip 58 can be placed on the tube 44 to seal the branch 40 of the Y-fitting. The cap used to permit injection of the heparin liquid also serves as a seal so that both branches are double sealed.

The next time the patient requires haemodialysis, it is a simple matter to insert a new inner lumen and to couple the structure to the necessary equipment. It will be appreciated that the inner lumen used for the second procedure need not have the tapered end to fit on the wire since the inner lumen passes into the vein inside the outer lumen which is already positioned in the vein. It is therefore possible to use a somewhat similar structure for the inner lumen for the second and subsequent uses of the cannula.

In the preferred embodiment the outer lumen 26 is of polytetrafluoroethylene having an internal diameter .125 in. and an external diameter .155. The inner lumen is made of polyethylene having an inner diameter .075 in. and an outer diameter of .092 in. The connector 34 and tubes 44, 48 are of a medical grade silicone rubber and the Y-connector is made of polypropylene.

It will be appreciated that the dimensions used for the tubing can vary within the limitations of providing adequate flow and insertion into the subclavian vein. If the structure is to be used elsewhere on a human, then

similar parameters will have to be considered in relation to the specific use of the cannula.

The outer lumen 26 is preferably of a radio-opaque material to permit X-ray. If the structure is transparent to X-ray then some identifiction band will have to be applied to the outer-lumen.

It is a significant feature of the present invention that although two lumens are used, in the period between treatments there is a minimized risk of blood clotting and a simplified procedure in that heparin containing physiological saline solution need be inserted in one side of the Y-fitting only. In previously suggested structures, it was not possible to remove the inner cannula and it was necessary to provide heparin in both the inner and outer cannulae. Further, without removal of the inner cannula it is not foreseen how it would be possible to avoid stagnant blood appearing somewhere between the two cannulae with resulting risk of clotting. Also, because the present structure has sufficient inherent rigidity, it is unnecessary to use an obturator. Previously suggested structures have required an obturator to ensure that the outer cannula does not kink during insertion. It would be appreciated that in materials of this type, once the tube has kinked, the weakness resulting from the kinking causes it to collapse very readily. Yet a further advantage of this structure is

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that it can be inserted over the wire used in the Seldinger techinque taking advantage of the weak but small outer end of the inner lumen because this is supported on the wire during insertion. There is therefore a progressive enlargement during insertion, beginning with the wire, followed by the inner lumen and then by the outer lumen. This is advantageous in stretching the tissue and providing a clean insertion.

It will also be appreciated that because the inner lumen has been removed, the sealing of the tube 48 is improved. It is undesirable to attempt to seal a tube which contains a further tube. No device can ensure proper sealing and yet, where a dual lumen is concerned, such sealings have been attempted. With the present structure once the inner lumen has been removed, then adequate sealing can be provided simply both at the tube 48 and at the outer end of the first part 50 of the luer connector.

It will be appreciated that the invention can take many forms within the scope of the accompanying claims and that the embodiment described is a preferred embodiment which is explarary of these variations.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A dual lumen cannula for use in haemodialysis by inserting the cannula into the subclavian vein of a patient to contemporaneously remove blood from the vein for treatment and to return treated blood to the vein downstream from the point of removal, the cannula comprising:

an elongated tubular outer lumen having a smooth outer surface and being of a material suitable for residing in the subclavian vein and adjacent tissue for extended periods of time, the outer lumen having a residual curvature similar to that of the portion of the vein receiving the cannula and being sufficiently flexible to be straightened during insertion without damage or kinking, and defining a tapered distal end portion and openings adjacent this end portion to withdraw blood from the vein;

an outer portion coupled to an end opposite said end portion of the outer lumen and including two branches communicating with the outer lumen;

an elongated tubular inner lumen adapted to reside essentially inside one of said two branches of the outer portion and inside the outer lumen, the inner and outer lumens and the outer portion being proportioned to permit flow of blood about the inner lumen and through the outer lumen and outer portion, the inner lumen including means for coupling the inner lumen to said one branch of the outer portion to seal the space between this portion and the inner lumen and being proportioned to project

outwardly of the tapered end portion of the outer lumen which tapered end portion fits snugly about the inner lumen in sealing engagement therewith, the inner lumen also defining openings outside the outer lumen for returning treated blood to the vein downstream of the aforementioned openings in the outer lumen.

2. A dual lumen cannula claimed in claim 1 in which each of the two branches of the outer portion includes a flexible tube capable of being nipped for sealing purposes after removal of the inner cannula and between haemodialysis treatments.

3. A dual lumen cannula for use in haemodialysis by inserting the cannula into the subclavian vein of a patient to contemporaneously remove blood from the vein for treatment and to return treated blood to the vein downstream from the point of removal, the cannula comprising;

an elongated tubular outer lumen having a smooth outer surface and being of a material suitable for residing in the subclavian vein and adjacent tissue for extended periods of time, the outer lumen having a residual curvature similar to that of the portion of the vein receiving the cannula and being sufficiently flexible to be straightened during insertion without damage or kinking, and defining a tapered distal end portion and openings adjacent this end portion to withdraw blood from the vein;

an outer portion coupled to an end opposite said end portion of the outer lumen and including two branches communicating with the outer lumen;

an elongated tubular inner lumen adapted to reside essentially inside one of said two branches of the outer portion and inside the outer lumen, the inner and outer lumens and the outer portion being proportioned to permit flow of blood about the inner lumen and through the outer lumen and outer portion, the inner lumen including means for coupling the inner lumen to said one branch of the outer portion to seal the space between this portion and the inner lumen and being proportioned to fit snugly inside the tapered end portion of the outer lumen in sealing engagement therewith, the inner lumen also defining at least one opening outside the outer lumen for returning treated blood to the vein downstream of the aforementioned openings in the outer lumen.

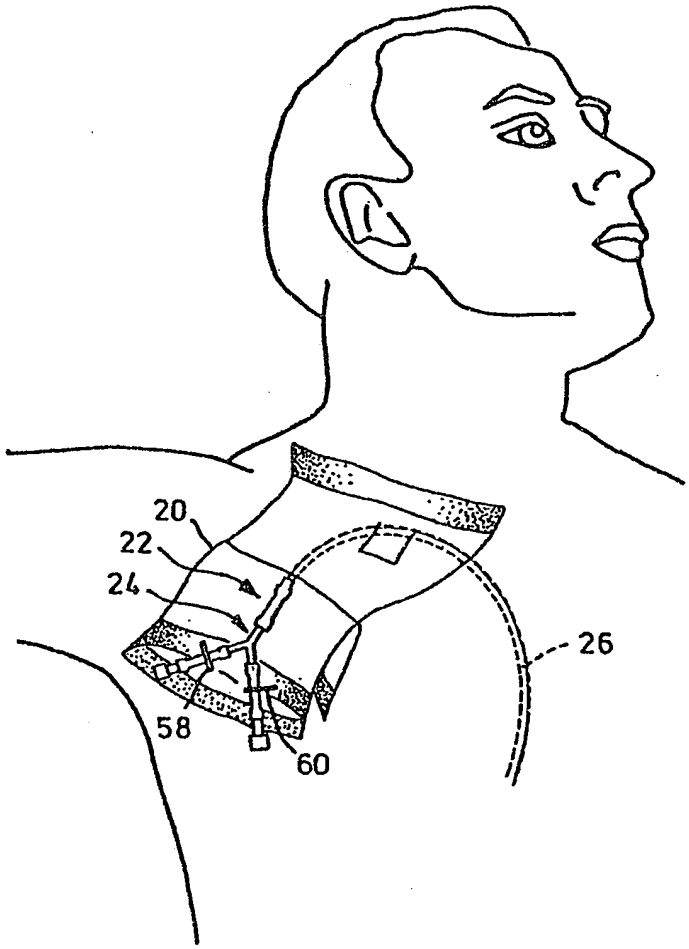

FIG. 1

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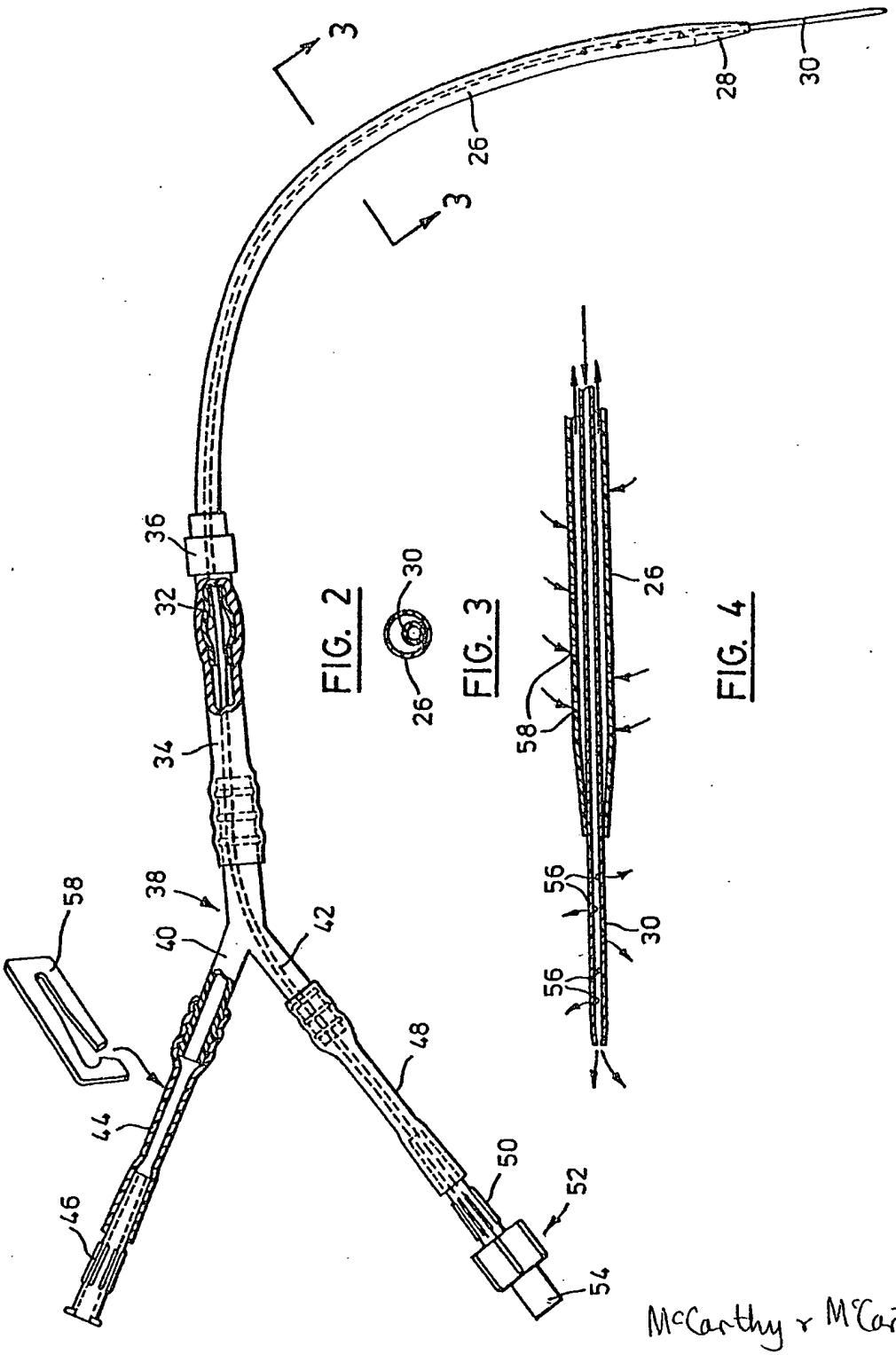

FIG. 2

FIG. 3

FIG. 4

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